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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,313	09/24/2001	Gunther Berndl	0050/49860	8414

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EXAMINER
YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
1615	13

DATE MAILED: 09/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/937,313	Applicant(s) BERNDL ET AL.	
	Examiner Micah-Paul Young	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Acknowledgment of Papers Received: Notice of Appeal sated 6/18/03. Request for Continued Examination and Amendment/Response dated 8/26/03.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 recites the limitation "other conventional tableting excipients" in the last line of the claim. This limitation makes it unclear what particular tableting excipients are being claimed, since conventions change with time. It is impossible to determine the total scope of the claim since conventions change with time, at time excluding or including certain elements. What is conventional today may not be conventional in the future. Applicant may cancel or amend the claim to overcome this rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 10, 15, 18 – 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Staniforth et al (USPN 5,741,524). The claims drawn to a process of making an excipient by spray-drying a solution of a polymer and a surface active agent in order to make a free-flowing powder. Also the surfactant can be selected from ethoxylated sorbitan fatty acids esters. The excipient further includes dyes, waxes and other common tableting agents. The excipient has a particle size between 10 and 1000 microns.

Staniforth teaches an improved excipient for tableting. The excipient can be wet-granulated and dried using known methods such as tray drying, spray drying, etc. (col. 2, lin. 14 – 23), though it is preferred that the product is spray dried (col. 14, lin. 28 – 32). The excipient includes a non-ionic surface-active agent. The excipient further includes dyes and other tableting agents (col. 12, lin. 11 – 40). The particles of the resultant free-flowing powder are between 10 and 1000 microns (col. 14, lin. 51 – 60). These limitations render the claims anticipated.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 11 – 14, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staniforth et al (USPN 5,741,524) in combination with Khan et al (USPN 4,806,358) and Sutton et al (USPN 5,993,805).

As discussed above Staniforth discloses a process for making a free-flowing excipient where the polymer and surfactant are spray-dried together. The reference however differs slightly in the concentrations of the polymer and the surfactant. The reference discloses a process producing identical particles within the same range and within the same field of endeavor as that of applicant. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See* In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various pharmaceutical compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See* In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

Also the reference suggests that the HLB of the surfactant can be at least 10 (col. 10, lin. 30). Though the preferred non-ionic surfactant has an HLB of 15.6, lower values are acceptable. Kahn et al discloses a formulation of polyvinylpyrrolidone (PVP) and microcrystalline cellulose where the surfactant is a TWEEN with an HLB between 10 and 13 (col. 2, lin. 13 – 30).

Another difference in the reference is the surfactants recited in claim 16. Staniforth suggests the use of fatty acid esters, and soybean lecithin as possible surfactant. Sutton et al also suggests these surfactants, along with glycerol-polyoxyethylene ricinoleate (col. 7 – lin. 40 – lin. 65). The formulation of Osborne comprises polyvinylpyrrolidone (PVP) and microcrystalline cellulose in a free-flowing excipient used for compressed tablets where the powder is spray-dried with a surfactant (examples).

Taking the art into consideration it would have been obvious to a skilled artisan to combine the teachings of Staniforth, Sutton and Kahn. Staniforth would have provided the process for making the free-flowing excipient with improved compressibility properties. A skilled artisan would have been motivated to substitute the microcrystalline cellulose of Staniforth with the PVP of either Kahn or Sutton since both compounds are known for their compression properties and preferred use in tableting. A skilled artisan would have been motivated to use the surfactants of Sutton in order to properly stabilize the solution and provide a more cohesive excipient. It would have been obvious to a skilled artisan to substitute the components of Kahn and Sutton into the process of Staniforth with an expected result of a modified PVP excipient with improved compressibility.

Response to Arguments

4. Applicant's arguments with respect to claims 1-9 have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600